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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,367	02/23/2004	Thomas Rausch	P/2107-248	8977

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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER

KALLIS, RUSSELL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,367	RAUSCH, THOMAS	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-15 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/762,782.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/23/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 is drawn to sequences that have 80% identity to the endogenous sequence and thus fails to further limit the claim from which it depends.

Priority

The priority claimed at the beginning of the specification must be amended to include the issued patent. "This is a continuation-in-part application of U.S. Patent Application No. 09/762,782, filed March 30, 2001, now U.S. Patent 6,784,339."

Drawings

The drawings are objected to because Figure 6 appears to be a photo copy of poor quality and is not suitable for publication because the text is blurred and contains matrix dots of a low quality reproduction. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be

Art Unit: 1638

necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On page 26 line 12, the German "gegen" should be translated to the English "against"..

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a process for producing a transgenic plant where the seed have an increased amount of reserves by transforming a plant with any sequence of unspecified specific activity expressed during seed development in flowers with young ovules; wherein the

Art Unit: 1638

expression of the endogenous invertase inhibitor protein is reduced or eliminated during seed development.

Applicant does not describe any sequence expressed during seed development in flowers with young ovules other than the apoplastic invertase inhibitor gene from tobacco and rapeseed.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of sequences expressed during seed development in flowers with young ovules. Applicants only describe invertase inhibitor proteins from tobacco. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of sequence expressed during seed development in flowers with young ovules. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for nucleotide sequences expressed during seed development in flowers with young ovules, it remains unclear what features identify the broadly claimed genus. Since the genus of nucleotide sequences expressed during seed development in flowers with young ovules has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Sequences that have 80% sequence identity or complementarity to invertase inhibitor sequences expressed during seed development in flowers with young ovules encompass naturally occurring allelic variants, mutants of invertase inhibitors, as well as sequences encoding proteins having no known invertase inhibitor activity, of which Applicant is not in possession.

Accordingly, the specification fails to provide an adequate written description to support the genus of nucleotide sequences encoding invertase inhibitor proteins encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 1-6 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for producing a transgenic plant where the seed have an increased amount of reserves by transforming with the isolated endogenous apoplastic invertase inhibitor coding sequence in either sense or antisense orientation, bearing seed with increased reserve content, does not reasonably provide enablement for a process of inhibiting invertase in a plant by transforming the plant using any sequence expressed during seed development in flowers with young ovules other than by transformation with an apoplastic invertase inhibitor protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant broadly claims a process for producing a transgenic plant where the seed have an increased amount of reserves by transforming a plant with any sequence of unspecified specific activity expressed during seed development in flowers with young ovules; wherein the

Art Unit: 1638

expression of the endogenous invertase inhibitor protein is reduced or eliminated during seed development.

Applicant teaches isolation of cell wall invertase, peptide sequencing of isolated cell wall invertase protein, cloning partial and full length cDNA from a cDNA library or cDNA bank (pages 17-19); sense and antisense transformation of tobacco with the gene encoding apoplastic tobacco invertase inhibitor by *Agrobacterium tumefaciens* mediated transformation using sense and antisense constructs (pages 19-23); determination of increased seed dry weight, stored oil, and total protein in tobacco transformed with an antisense apoplastic invertase inhibitor construct (pages 21-22) and increased dry weight and stored oil content in sense transformed tobacco plants (page 26).

Applicant does not teach isolation of any nucleic acid sequence expressed during seed development in flowers with young ovules or any invertase inhibitor coding sequences other than an apoplastic cell wall invertase inhibitor sequence from tobacco that when transformed into a plant resulted in seeds with an increase in reserve content in any plant species other than the tobacco apoplastic cell wall inhibitor encoding nucleic acid sequence.

An important consideration in genetic engineering for altered starch or protein content by altering gene expression is knowing or determining when and where the gene or gene product of interest is expressed. In studies by Link M. *et al.*, (FEBS Letters; 2004, Vol. 573 pp. 105-109) in *Arabidopsis*, the vacuolar form of the invertase inhibitor does not show expression in the seeds of the plant (see Abstract and page 107 figure 3 and page 108, column 1 lines 14-16), while the cell wall invertase inhibitor is expressed in the flower and seeds (see Abstract and page 107 figure 3), indicating that the apoplastic or cell wall invertase inhibitor protein in *Arabidopsis* is

Art Unit: 1638

expressed during seed development, also seen in other plants species (Rausch T. *et al.* Biochimica et Biophysica acta, 2004; Vol. 1696, pp. 253-261). Further, since the apoplastic and vacuolar forms of the invertase inhibitor have very divergent sequence identities the vacuolar form of invertase inhibitor would not function in either a sense or antisense suppression of the endogenous cell wall apoplastic form of invertase inhibitor; and thus the vacuolar invertase inhibitor coding sequence is an unlikely and unsuitable candidate for engineering reserve accumulation in seeds of plants transformed therewith.

Given the lack of support in the specification for making and isolating vacuolar invertase coding sequences or any non-exemplified sequence expressed during seed development, that when transformed into a plant produces seeds with increased reserve levels; and given that Applicant has provided no working examples of plants transformed with vacuolar invertase inhibitor coding sequences or any non-exemplified and unspecified sequence expressed during seed development that showed an increase in seed reserve material; and given that the state of the art does not recognize that vacuolar invertase inhibitors are expressed in seeds or have any degree of homology required for a sense or antisense suppression of the endogenous apoplastic or cell wall invertase inhibitor, including any unspecified and non-exemplified sequences expressed during seed development that reflect the breadth of the claims; and given the unpredictability in the art, undue trial and error experimentation would be needed to practice the invention. Therefore, the invention is not enabled for the scope set forth in the claims.

Art Unit: 1638

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

The term "80% sequence identity" in claim 6 is a relative term that renders the claim indefinite. The term "80% sequence identity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is indefinite because it claims percent identity to sequences, the identities of which are not disclosed (i.e. a sequence identifier), and thus there is no measure of the metes and bounds of 80% sequence identity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-22 of U.S. Patent No. 6,784,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

Art Unit: 1638

claims of the instant application are broadly drawn to a process of transforming a plant with an antisense or sense plant invertase inhibitor nucleic acid to reduce the endogenous invertase inhibitor protein during seed development. Thus, the embodiments of the inventions of Claims 1-22 of U.S. Patent 6,784,399 fall within the scope of Claims 1-15 of the instant application.

All claims are rejected.

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claims are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a process of antisense or sense suppression of endogenous cell wall or apoplastic invertase inhibitor protein that would result in the increase of seed reserve material when transformed into a plant.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.
September 26, 2006

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Russell Kallis". The signature is written in a cursive, flowing style.